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(54) Title: NUTRITIONAL FROZEN DESSERT AND METHODS OF MANUFACTURE

(57) Abstract: The invention relates to methods for preparing nutritional frozen desserts having palatable characteristics and comprising vitamins and minerals. The invention also includes the nutritious frozen desserts, and methods of treating subjects using the frozen desserts.

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**NUTRITIONAL FROZEN DESSERT AND METHODS OF MANUFACTURE**

5           This application claims priority to U.S. Provisional Application Serial No. 60/292,987 filed May 23, 2001 entitled Nutritional Frozen Dessert and Method of Manufacture and U.S. Provisional Application Serial No. 60/301,566 filed June 28, 2001 entitled Nutritional Frozen Dessert and Method of Manufacture, both currently pending.

**FIELD OF THE INVENTION**

10           The invention relates to frozen dessert formulations and methods of producing the same. In particular the invention relates to frozen desserts such as ice cream having enhanced nutritional properties.

**BACKGROUND OF THE INVENTION**

15           Frozen dessert products such as ice cream have been enjoyed by consumers for years, but generally have not been considered to be nutritious products. Many attempts have been made to develop ice cream which retains its desirable taste but which have improved nutritious properties. For instance, several attempts have been made to  
20           produce ice cream having low levels of fat. Often, these modified ice creams sacrifice taste for improved nutritional properties, and as a result are not accepted by consumers.

          Methods for manufacturing and formulating ice cream are well known. In general, the methods involve the mixing of ingredients, followed by processing and  
25           freezing. Briefly, milk of varying fat proportions and/or hydrated milk powder is combined with cane sugar or derivatives and/or corn syrups, modified food starches, maltodextrins, stabilizing gums and emulsifiers. Ice cream with high levels of fat also include the addition of cream to the mix. After the ingredients are mixed, the material is pasteurized, homogenized and chilled. This process material preferably is stored for  
30           a period of time ranging from a few hours to 24 hours. After the storage step a flavoring component is added to the mixture, if desired. If chocolate ice cream is being prepared, cocoa is added in the first mixing step and does not need to be added after the

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storage. Following the flavoring step the material is partially frozen, packaged and then completely frozen.

The percentage of solids incorporated into the mixture at the first step is generally carefully analyzed prior to pasteurization. It is important to confirm the amount of solids in the ice cream in order to determine the required pasteurization temperature and time as well as for quality assurance of the batching procedure. The percentage of solids at that stage of the method is an indication of the density of the product. The final density will depend on the amount of air incorporated when freezing. Solids exceeding 45% are typically considered unsuitable or problematic for commercial manufacturing. High percentages of solids and viscous mixtures increase the probability of "burn on" during pasteurization and/or clogging and disrupted production flow during cooling. As solids are cooked onto the pasteurization plates, off flavors may result causing spoilage of the entire mixture. Chocolate or dark mixes tend to be more forgiving because of the strong flavor characteristic of the chocolate. Generally, 45% solids is generally considered to be the standard manufacturing upper limit for ice cream mixes.

#### SUMMARY OF THE INVENTION

The invention relates in some aspects to an improved method for the preparation of nutritious ice cream. It has been discovered according to the invention that a fortified ice cream which is supplemented with macro- and/or micro- nutrients including, for instance, vitamins, minerals, oils, proteins, fibers, phytonutrients, prebiotics, probiotics, botanicals and nutraceuticals and which is palatable can be prepared. Even with the addition of all of these components, the ice cream maintains favorable organoleptic properties. The invention is based, at least in part, on the surprising finding that ice cream containing many of these nutrients can retain favorable organoleptic properties if prepared according to specific methods. The methods of the invention allow for the inclusion of solids not traditionally found in frozen desserts, while retaining standard operating procedures and manufacturing equipment established for commercial manufacturing. The methods utilize acidulants and other components such as high dextrose equivalent sweeteners and/or other

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concentrated artificial or natural derived sweeteners. A preferred sweetener is crystalline fructose.

Thus, in some aspects, the invention is a method for making a nutritious frozen dessert. The method involves mixing a base component, a nutrient core including at least one micronutrient selected from the group consisting of folate, magnesium, phosphorus, zinc, selenium, iron, copper, chromium, molybdenum, manganese, iodine, potassium, sodium, vitamin A, vitamin C, vitamin D, vitamin B1, vitamin B2, vitamin B3, vitamin B5, vitamin B6, vitamin B12, vitamin E, vitamin K, biotin, and combinations thereof, and an acidulant in a mixing chamber to produce a prepasteurized mixture, pasteurizing the prepasteurized mixture, and freezing the pasteurized mixture to produce the nutritious frozen dessert. In some embodiments, the base component is dairy, soy, rice, oats, almonds, sesame, sunflower, lupine, taro or a combination thereof. In other embodiments, the prepasteurization mixture includes from about 0.1% to about 80% of the daily value of calcium, magnesium, phosphorus, zinc, vitamin A, vitamin D, and from about 0.1% to about 100% of the daily value of folate, vitamin B1, vitamin B2, vitamin B3 and from about 0.1% to about 200% of the daily value of vitamin B6, Vitamin B12, vitamin E, and from about 0.1 % to about 250% of the daily value of vitamin C. The percent daily value is based on a 2000 calorie diet.

The acidulant in some embodiments is added in a range of about 0.1 weight percent to about 0.6 weight percent. Acidulants include but are not limited to citric acid, malic acid, adipic acid, phosphoric acid, tartaric acid, ascorbic acid, lactic acid, lemon juice concentrate, and combinations thereof.

In other embodiments the nutrient core added to the mixture includes per serving size: from about 5 % to about 50 % of the daily value of Folate, Calcium, Magnesium, Phosphorus, Zinc, Vitamin A, Vitamin D, and Vitamin B1; from about 5 % to about 100 % of the daily value of Vitamin C and Vitamin E.

In yet other embodiments the nutrient core added to the mixture includes per serving size: about 50 % of the daily value of Folate; about 40 % of the daily value of Calcium and Vitamin D; about 33 % of the daily value of Magnesium, Zinc, and Vitamin A; about 25 % of the daily value of Phosphorus and Vitamin B1; and about 100 % of the daily value of Vitamin C and Vitamin E.

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The method in other embodiments involves the addition of a sweetener to the pre-prepasteurized mixture. The sweetener may be a high dextrose sweetener, an artificial sweetener, a highly concentrated sweetener. For instance, the sweetener may be crystalline fructose, aspartame, saccharin, sucralose, D-tagatose, or stevia. In another embodiment, the sweetener is added to the prepasteurized mixture in an amount sufficient to produce the range of about 0.02 weight percent to about 22.0 weight percent of the product. In preferred embodiments, the sweetener is a crystalline fructose.

The method may additionally include the step of adding a flavoring agent. In one embodiment, the flavoring agent is chocolate and the cocoa is added to the prepasteurized mixture. In other embodiments, the flavoring agent is a non-fruit flavoring agent, such as, coffee, vanilla, mocha, mint, caramel, green tea, hazelnut, ginger, coconut, pistachio, or rose. In yet other embodiments, the flavoring agent is a fruit flavor such as mandarin, orange, strawberry, banana, raspberry, mango, passion fruit, etc. The flavoring agent may be added after the pasteurization step in a flavor tank.

In yet other embodiments, the prepasteurized mixture includes macronutrients such as proteins, dietary fiber, fatty acids.

In other aspects, the invention relates to a method for preparing a non-fruit flavor nutritious frozen dessert. The method involves mixing a base component and a nutrient core including at least one micronutrient selected from the group consisting of: Folate, Magnesium, Phosphorus, Zinc, selenium, iron, copper, chromium, molybdenum, manganese, iodine, potassium, sodium, Vitamin A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B6, Vitamin B12, Vitamin E, vitamin k, biotin and combinations thereof to produce a mixture, pasteurizing and homogenizing the mixture, adding an acidulant and a non-fruit flavoring agent to the pasteurized mixture, and freezing the flavored mixture to produce a non-fruit flavored frozen dessert.

In other aspects, the invention relates to a nutritious frozen dessert. The nutritious frozen dessert includes a base component, a non-fruit flavoring, a nutrient core of at least 1% by weight of the dessert product, wherein the nutrient core includes at least one micronutrient selected from the group consisting of: Folate, Magnesium,

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Phosphorus, Zinc, Vitamin A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B6, Vitamin B12, Vitamin E, Manganese, and combinations thereof; a sweetener, and an acidulant. In some preferred embodiments the nutrient core is at least 1.6% by weight of the dessert product. In other preferred embodiments, the nutrient core is at least about 2.4% by weight of the dessert product. In some embodiments, the nutrient core is about 4% by weight of the dessert product. In some embodiments the base component is dairy (e.g., milk or cream), soy, rice, oats, almonds, sesame, sunflower, lupine, taro, or combinations thereof.

In preferred embodiments the dessert includes per serving size: from about 0.1 % to about 80 % of the daily value of Calcium, Magnesium, Phosphorus, Zinc, Vitamin A and Vitamin D; from about 0.1 % to about 250 % of the daily value of Vitamin C; from about 0.1 % to about 100 % of the daily value of Vitamin B1, B2, B3, and Folate; from about 0.1 % to about 200 % of the daily value of Vitamin B6, Vitamin B12, and Vitamin E. The percent daily value is based on a 2,000 calorie diet.

In other embodiments the dessert includes per serving size: from about 5 % to about 50 % of the daily value of Folate, Calcium, Magnesium, Phosphorus, Zinc, Vitamin A, Vitamin D, and Vitamin B1; from about 5 % to about 100 % of the daily value of Vitamin C and Vitamin E.

In yet other embodiments the dessert includes per serving size: about 50 % of the daily value of Folate; about 40 % of the daily value of Calcium and Vitamin D; about 33 % of the daily value of Magnesium, Zinc, and Vitamin A; about 25 % of the daily value of Phosphorus and Vitamin B1; and about 100 % of the daily value of Vitamin C and Vitamin E.

The frozen dessert includes a sweetener. The sweetener may be, for instance, crystalline fructose, a high dextrose sweetener, a highly concentrated sweetener or an artificial sweetener. In some embodiments, the sweetener is present in the range of about 0.02 weight percent to about 22.0 weight percent. In preferred embodiments, the sweetener is a crystalline fructose.

The frozen dessert also includes a non-fruit flavoring agent. In one embodiment, the flavoring agent is chocolate. In other embodiments, the non-fruit flavoring agent is coffee, vanilla, mocha, mint, caramel, green tea, hazelnut, ginger, coconut, pistachio, or rose.



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In yet other embodiments, the frozen dessert includes one or more macronutrients such as proteins, dietary fiber, fatty acids.

In other aspects, the invention is a method for treating a subject by administering to the subject a frozen dessert product prepared by the method described herein. In one embodiment, the subject is a diabetic. In yet other embodiments, the subject is an elderly subject.

Each of the limitations of the invention can encompass various embodiments of the invention. It is, therefore, anticipated that each of the limitations of the invention involving any one element or combinations of elements can be included in each aspect of the invention.

#### DETAILED DESCRIPTION

The invention is based, in part, on the discovery that acidulants if added in the appropriate concentration at the appropriate time during the process of preparing a highly fortified frozen dessert such as an ice cream product can significantly alter the organoleptic properties of the frozen dessert. Thus, the invention encompasses a nutritionally fortified frozen dessert product having favorable organoleptic properties characteristic of comparatively low nutrient standard ice cream like desserts. A frozen dessert product as used herein is a product which is solidified under freezing conditions to a hard pack or a soft, semi-fluid or spoonable consistency. The frozen dessert products include, for example, ice cream, sherbet like variations, or variations of ice cream having non-dairy base components such as rice or soy or combinations of non-dairy and dairy base components.

The frozen dessert product may be fortified with vitamins, minerals, proteins, amino acids, essential and non-essential fatty acids, carbohydrates, dietary fibers, fiber derivatives, ribose, plant sterols, prebiotics, botanicals, phytonutrients, flavonoids, and other food constituents and/or engineered analogs. The invention allows for the significant reduction of off flavor impact; off colors and textures created by macro and micro-nutrients used to fortify the ice cream. Because ice cream remains principally a pleasure food, these types of ingredients are not traditionally found in frozen desserts because of their unpalatable characteristics and well known resistance to masking. Also, the serving size for ice cream has been established by the FDA as "1/2 cup" or 4

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fl oz (118ml). This contrasts to the typical serving size of 8 fl oz (237ml) for liquid nutritional products used as meal supplements and/or replacements. The smaller serving size for ice cream makes it very difficult to provide with ice cream comparable, near comparable, or superior nutritional value to the more voluminous liquid nutritional. The use of ice cream as an effective nutrient delivery system has been hampered by the small volume serving size and the necessity to provide ice cream satisfaction. The small volume serving size results in concentrating the off flavors characteristic of the micronutrients as well as potentially adding other solids found in proteins, fats, carbohydrates and/or other supplemental ingredients. This concentration of solids, in addition to concentrating the off flavors, increases the likelihood that the percentage of solids in the fortified ice cream mix will exceed the level of solids tolerated in commercial ice cream production. The two formulating challenges in developing a fortified ice and/or frozen ice cream like dessert are "taste" and "space." These problems have been effectively overcome by the methods and discoveries of the invention.

It has been discovered, according to the invention, that acidulants when used in the manner described herein can lead to the development of a fortified frozen dessert which includes nutrients at levels largely comparable and/or even exceeding the values found in established liquid meal supplements, such as market leader Ensure®. This was surprising because of the disparity in serving sizes between ice cream and liquid nutritional. The frozen dessert product of the invention provides significantly more nutritional value ounce for ounce (by volume) than most liquid meal supplements. Additionally, certain embodiments of the frozen dessert invention include largely comparable or superior nutritional value to that of standard liquid meal supplements per serving, or in effect one-half the volume. This is surprisingly achieved while maintaining the desirable and demanding organoleptic properties expected of ice cream. For example, the following table provides a comparison of an example of a fortified ice cream product according to the methods of the invention with commercially available Ensure®.

Table 1

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	Ice Cream of the Invention	Ensure®
Serving Size	4 Fluid Ounces	8 Fluid Ounces
Calories	200	250
Protein (g)	6-9	9
Fat (g)	8	6
Carbohydrate (g)	24	40
Fiber (g)	2	>1
	% DV	% DV
Vitamin A	33	25
Vitamin C	100	50
Vitamin D	40	25
Vitamin E	100	25
Vitamin B1	25	25
Folate	50	25
Calcium	40	30
Magnesium	33	25
Phosphorous	25	30
Zinc	33	25

Table 1 demonstrates that the ice cream formulation of the invention is a potent nutrient delivery system that is as nutrient dense as a standard liquid nutritional composition, but which only requires half the volume. Percent Daily Values are based on a 2,000 calorie diet. It has also been demonstrated that this material has favorable organoleptic characteristics (see Examples, Market Test and Clinical Study).

The method of the invention is based at least partially on the discovery of a method for formulating the frozen dessert product in a manner that allows for additional ingredients without exceeding the percentage of solids established for commercial ice cream manufacturing. The addition of vitamins and minerals to a commercial dairy mix, while enhancing nutritional value also add a wide range of unappetizing flavors, including, but not limited to, bitter, metallic, and sour. The degree of adverse impact depends upon the level of fortification with these ingredients. Attempts to increase the sweetness of ice cream with additional sugars to offset these unappetizing flavors is not effective. It was discovered according to the invention that simply adding sweeteners to overcome off flavors tends to result in over-sweetening and fails to overcome the unappetizing and unacceptable flavors. Those skilled in the art of conventional ice cream adjust relative sweetness up or down according to a given flavor profile. Chocolate flavors, for example, typically require more sweeteners than vanilla because of the added cocoa. However, this approach is inadequate for fortified

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ice creams. A fortified ice cream does require significantly more relative sweetness than a conventional ice cream, however, surprisingly, it was discovered that a non-flavor related acidulant added at the appropriate time during manufacture significantly reduces the amount of additional sweetener used and helps to mask characteristic off  
5 flavors contributed by supplemental ingredients. Also, in a preferred embodiment, in concert with the acidulant it was discovered that the utilization of a high dextrose equivalent (DE) sweetener such as crystalline fructose provides additional space or room for solids for example, micronutrients, supplemental nutrients and macronutrients. In this regard where space is needed the acidulant supports both the  
10 masking of undesirable flavors and the reduction of incremental sweetness required.

In general, the method is accomplished by mixing a base component with the nutrients, sweeteners, the acidulant, and optionally emulsifiers, and stabilizers in a mixing tank. Once this mixture is complete, the material is pasteurized, homogenized, chilled and optionally stored with gentle agitation under refrigeration for several hours  
15 to a day in a holding tank(s). The entire mixture or a portion of it may then be moved into a flavor vat or tank where optionally a flavor is mixed in. The flavored mixture is checked for taste and color properties and then partially frozen and put into containers or made into novelties. The base component is an important part of the frozen dessert product, as it forms a large percentage of the formulation by weight.

20 The base component may be dairy or non-dairy. A non-dairy component is useful, for instance, for individuals who are lactose intolerant or have allergies to dairy. Dairy based components include, but are not limited to, cream, whole milk, concentrated whole milk, evaporated whole milk, sweetened condensed whole milk, superheated condensed whole milk, dried whole milk, skim milk, concentrated skim  
25 milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, non-fat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, concentrated skim milk from which a portion of the lactose has been removed, casein, modified casein, modified whey, whey protein concentrate, caseinate,  
30 and dehydrated milk, whey protein isolates, hydrolyzed milk protein, denatured milk proteins. Non-dairy based components include, but are not limited to legume, seed and nut derived protein sources such as soy milk, concentrated liquid soymilk, soy milk

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powder, soy concentrate, soy isolate, rice milk, rice protein concentrate, oats, almonds, sesame, sunflower, cashews, taro and lupine. The base component of a frozen dessert product may be composed of a single dairy or non-dairy base component or a combination of two or more of these components.

5           An acidulant as used herein is an acidifying agent that is safe for consumption. Acidulants include, but are not limited to, citric acid, malic acid, adipic acid, phosphoric acid, tartaric acid, ascorbic acid, lactic acid, and lemon juice concentrate. A preferred acidulant is citric acid.

10           The optimal time for adding the acidulant to the mixture is prior to the pasteurization process. The acidulant may be mixed with the micronutrients prior to their addition to the base component or may be administered directly to the base component and other components of the mixture. Preferably, the acidulant is premixed with a portion of the sweetener in a dry form and subsequently added to the base mix. Optimal results were achieved when the acidulant was added in this manner. Although  
15           applicant is not bound by any mechanism, it is believed that the premixture of the acidulant with the sweetener reduces the potential of the acidulant to cause curdling when it comes into contact with the base component, if the base component is a dairy product, and that dispersion is optimized by this premixture. The acidulant may also be

20           It was discovered that the acidulant could be added after the pasteurization process or at the flavor vat in some ice cream formulations, but that the organoleptic properties were reduced somewhat by this delayed addition of the acidulant. Thus, it was discovered, quite unexpectedly, that the timing and method for introduction of the acidulant to the mixture had dramatic impact on the organoleptic properties of the  
25           resultant frozen dessert product.

          Although some methods for manufacturing tart ice cream flavors and other frozen dessert products have utilized acids such as citric acid, the acid is not added at the appropriate time or in the appropriate concentration as was found to be necessary to mask the unpalatable flavor of the nutrient mixture according to the invention. It is  
30           known, when formulating a fruit flavor, ice cream makers purchase adjusted fruit puree's and concentrates that can be added at the flavor tank without requiring additional ingredients to enhance the natural tartness of the flavor. Alternatively, citric

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acid is sometimes mixed with fruit purees, concentrates and flavorings, such as raspberry, which are added to the ice cream mixture after pasteurization in the flavor tank. The acid is added to support the natural acidic tart flavor of the fruit. It is known to add citric acid at the flavor vats for sherbets and water ices at levels between  
5 approximately 100mg – 300mg per serving. Sherbet and water ice formulators add an acidulant at the flavor vat (in addition to fruit juices, flavors and colors) to, in effect, satisfy the need to include more solids, as sugars, to obtain a satisfactory texture.

In contrast, based on a micronutrient core representing approximately 2.5% by weight of the formulation, approximately 0.27% by weight of citric acid to as much as  
10 approximately 0.8 % and up to as much as 0.9% citric acid may be added in some embodiments of the present invention for masking unpalatable flavors, maintaining a pH range for the mix of about 6.3- about 7.1, and for flavoring. As the micronutrient levels increase, the level of acidulant may also need to be increased. In a preferred embodiment, the acidulant is added after the sugars, gums, emulsifiers, oils and other  
15 ingredients, and in close proximity to the vitamin and mineral mixture. In a more preferred embodiment, the acidulant is mixed with a portion of the sugars, or alternatively mixed with the micronutrients to reduce the probability of curdling for dairy based mixes and maximize the organoleptic properties. According to the invention, in the prepasteurization stage, anhydrous citric acid may range from about  
20 0.1 wt % to about 0.6 wt %. In one embodiment having a micronutrient core of approximately 2.5% by weight, the prepasteurization level of anhydrous citric acid is approximately 0.2% to approximately 0.4%. In a preferred embodiment, the anhydrous citric acid may be as low as about 0.27 wt % to as much as about 0.4 wt % of the frozen desert product. It is contemplated that those of skill in the art can identify levels of  
25 other acidulants for use in the prepasteurization stage. When a tart fruit flavor is desired, an acidulant may also be added at the flavor vat. In a fruit flavor embodiment, citric acid is added at 0.38% by weight at the prepasteurization stage, and about 0.39% acidulant is added at the flavor vat. For example, the total citric acid added to an orange flavor ice cream of the present invention is about 360 mg per 1/2 cup serving;  
30 and for a raspberry flavor ice cream of the present invention is about 750 mg per 1/2 cup serving. The amount of acidulant may vary depending on the make-up of the supplemental ingredients and the amount added as a percentage by weight. In another

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embodiment the acidulant is added at the prepasturization stage at approximately 0.1% to approximately 0.19%. In another embodiment, the acidulants used may be approximately 0.5% to approximately 1.1% at the prepasturization stage. These high levels threatened to curdle the dairy products, thus ruining the mixture. When the acidulant is added in close proximity to the vitamin and mineral mixture or with the vitamin and mineral mixture, the incidence of curdling is reduced and the organoleptic products are maximized. It is found that the organoleptic impact may be enhanced by adding the acidulant to the ice cream mix, white or chocolate, prior to pasteurization. Additional acidulant may also be added at the flavor vat to increase the natural tartness of a flavor. Surprisingly, it has been found that adding all the acidulant to the flavor vat instead of adding a portion of an acidulant to the prepasturization mix, results in unfavorable organoleptic properties.

Without the acidulant, and depending upon the level of fortification, fortified ice creams have significant unpalatable flavor that cannot be sweetened over or flavored over. As demonstrated in Table 2, a super premium ice cream includes a high percentage of solids (40%) as a result of the fat content. The addition of a micronutrient core at 2.5% by weight would present a major problem in super premium ice cream. Without the addition of the acidulant during mix making, the additional micronutrients would require increasing the sucrose added, for example, from 14% to perhaps 25% or more. An increase of 11% solids creates a formulation with solids greater than 53%, which far exceeds 45% solids, the upper limit generally recognized for commercial manufacturing, leaving no room for added proteins, fiber or other supplemental nutrients. Although the sugar would provide some relief from the unpalatable flavor, some of the off flavors would still be apparent, the ice cream would be excessively sweet, and the manufacturing process may be compromised. Additionally, the increase in sweeteners as well as the micronutrient core would far exceed the accepted range of percentage of solids (45%) generally accepted for manufacturing ice cream. The super premium template as conventionally considered is a non-starter for a commercially viable fortified ice cream formula that does not require equipment modifications. However, according to the present invention, the use of the acidulant in concert with a high DE sweetener such as crystalline fructose may allow the super premium ice cream to be fortified. For example, by adding the acidulant at

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0.28% and using a sweetener blend of approximately 11% fructose, 3% sucrose and 2% rice syrup, it is possible to reduce the total solids to 44.98%, still leaving no room for additional nutrients but expanding the potential for ice cream and ice cream like frozen desserts to deliver unique and beneficial meal supplemental support.

5

Table 2

	Super Premium 15% Butterfat	Premium 10% Butterfat	Low Fat 3% Fat	Formulated Frozen Dessert of the Invention
Serum Solids	10	10	10	8.5
Fat from Milk	15	10	3	3.45
Fat from Other Oils	0	0	0	3.3
Emulsifier	1	0.25	0.5	0.25
Sucrose	14	15	12	3.25
Fructose	0	0	0	11.25
Maltodextrin	0	0	6	2
Stabilizer	0.2	0.2	0.3	0.2
Micronutrient Pre-mix	0	0	0	2
Added Protein	0	0	0	4
Citric Acid	0	0	0	0.1-0.6
Fiber	0	0	0	1
Other Solids	0	0	0	1
Total Solids (%)	40.2	35.45	34.8	40.5

In the premium and low fat ice cream examples presented in Table 2 above, there is more room (34%-35% solids) for fortification than with super premium ice cream. The addition of a micronutrient core, however, would still necessitate a significant increase in relative sweetness which would result in the exceeding of the available percent solids in the ice cream. Additionally, the formulated ice cream would not have enough room for solids such as proteins, fibers, or other beneficial ingredients useful for further supplementing and fortifying the ice cream. Moreover, the off flavors would linger behind the sweetness and flavor profile. Increasing the sucrose to 25% to again attempt to accommodate the off flavors would immediately increase the solids to 45+%. Even doing so, without adding supplemental ingredients, would not result in a fortified ice cream that tastes and feels like ice cream. If a micronutrient core of 1% by weight of the formula could be added to ice cream, it is likely that less sweeteners



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would be needed than with the addition of 2% micronutrient core. However, the resultant ice cream product would still be excessively sweet and would not have as much nutrient fortification as can be achieved with the use of an acidulant. In contrast, the utilization of an acidulant and the utilization of high dextrose equivalent sweeteners and/or the use of super-concentrated sweeteners such as aspartame, sucralose and stevia along with an acidulant expands the space available for supplementation and improves the organoleptic characteristics. Making the adjustments in sweeteners and adding the acidulant pushes the total solids down to 39.23%, allowing room for other ingredients.

10       The use of the acidulant in the ice cream product produces a palatable result without the necessity for increasing the amount of sweeteners by weight in the ice cream. However, the choice of sweetener is likely to be determined by the amount of relative sweetness needed for satisfactory organoleptic results. A sweetener as used herein includes sugar, as well as sugar substitutes. Sugars include, but are not limited to, sucrose, dextrose, (glucose,) fructose, lactose, maltose, honey, invert sugar, corn  
15       syrup, high fructose corn syrup, rice syrup, grain syrup, maltodextrin, polydextrose, ologodextrin, cane based sweetener, beet based sweetener, etc. Artificial sweeteners, sugar substitutes and non-nutritive sweeteners include, but are not limited to, edible saccharin salts, aspartame, saccharine, alitame, acesulfame K, tagatose thaumatin,  
20       dihydrochalcones, cyclamates, steviosides, glycyrrhizins, synthetic alkoxy aromatics, such as dulcin, sucralose, stevia, suosan, miraculin, monellin, sorbitol, xylitol, talin, cyclohexylsulfamates, synthetic sulfamic acids, oximes, aspartyl malonates, succanilic acids, amino acid based sweeteners, and carboxylates such as 3-hydroxy-4-alkyloxyphenyl aliphatic carboxylates. Sweeteners may be incorporated in an amount  
25       up to approximately 22 percent by weight. In one embodiment, the sweetener is present in a range of about .02% - 22% preferably about from 13% to about 17% by weight of the frozen desert product. Some ingredients included as sweeteners may contribute relatively little sweetness but serve as, for example, bulking agents. Alternatively, "no sugar added" ice creams may incorporate non-nutritive sweeteners.  
30       In another embodiment, the sweetener may be present in a range of about 0.03% to about 13%, and may include, for example, stevia in combination with other sweeteners such as crystalline fructose, sucrose, and maltodextrin. Conversely, the sweetener may

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be present in a range of about 14% to about 22% and may include, for example, liquid sugar, corn syrup, sucrose and rice oligodextrin.

A preferred sweetener is crystalline fructose. Crystalline fructose is about 1.73 times sweeter than sucrose and has a low glycemic index. Fructose is not normally  
5 used in commercial ice cream preparation because it is known to depress the freezing point and also because it is more expensive. These drawbacks, however, are more than overcome by the advantages of fructose in the formulations of the invention.

The use of fructose allows for the significant increase in relative sweetness without increasing the actual percent of solids as sugar, such as sucrose, beyond the  
10 range typical of ice cream formulations. The level of fructose may be as high as 17% by weight or as low as 0% by weight if other sweeteners are used. In one embodiment the level of fructose is about 10% to about 12% by weight when used in conjunction with sucrose at about 3% to about 4% by weight and rice syrup at about 1.5% to about 3% by weight. In another embodiment the level of fructose is about 3% to about 4% by  
15 weight when used in conjunction with sucrose at about 3% to about 4% by weight, stevia at about 0.03% to about 0.04% by weight and 18DE malteodextrins at about 5% to about 10% by weight. The use of fructose significantly reduces the percent of solids in the ice cream formulation with respect to a sugar such as sucrose. This allows for the conservation of space for additional fortification ingredients.

20 In conventional ice cream, the total amount of sweetness expressed as sucrose typically varies from about 12% to about 20% and may range from about 13% to about 17%. In one embodiment of the present invention, when the micronutrient core is approximately 2.5% by weight of the formulation, the relative level of sweetness is about 21 % to about 30%, preferably from about 23% to about 27%, and more  
25 preferably about 23% to about 25%. In another embodiment the use of an acidulant such as citric acid in making the prepasturization mix allows for the reduction of sweetness by about 15% to about 25%. In yet another embodiment, when the micronutrient core is about 1.6% by weight of the formulation, the relative sweetness is slightly greater than about 20%. As shown in Table 2 above, the use of the  
30 combination of an acidulant and fructose in the formulated frozen dessert allows for the availability of space for solids in the ice cream such that protein, fiber, prebiotics, vitamins, and other nutrients could be added. The total solids even with the addition of

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all these micro and macronutrients is only 40.5% total. Thus, additional nutrients could be added if desired.

A nutrient as used herein refers to micronutrients, macronutrients, concentrated food constituents, conditionally essential amino acids, digestive enzymes,

5 phytonutrients, botanicals, prebiotics, probiotics, flavonoids, isoflavones, plant sterols, polyphenols, accessory nutrients such as n-acetylcysteine, alpha lipoic acid, co-enzyme Q, carotenoids, ribose, creatine, betaine, alpha ketoglutarate, beta glucans, choline, serine, nucleotides, ATP. Micronutrients include, but are not limited to, vitamins and minerals, such as, those recognized by the Food and Drug Administration in the Code

10 of Federal Regulations 21 C.F.R 101.9. Non limiting examples of micronutrients include folate, calcium, magnesium, phosphorus, zinc, vitamin A, vitamin C, vitamin D, vitamin B1, vitamin B2, vitamin B3, calcium phosphate or acetate, magnesium phosphate or aspartate, magnesium citrate or glycinate, magnesium orotate or succinate, magnesium arginate tribasic; dipotassium phosphate dibasic; magnesium

15 sulfate or oxide; salt (sodium chloride); potassium chloride or acetate; ascorbic acid; ferric orthophosphate; alpha-tocopheryl acetate; niacinamide; zinc sulfate or oxide; calcium pantothenate; copper gluconate; beta-carotene; pyridoxine hydrochloride; thiamin mononitrate; biotin; chromium chloride or picolinate; potassium iodide or citrate; sodium selenite; sodium molybdate; phylloquinone; vitamin D3 ;

20 cyanocobalamin; copper sulfate; vitamin B6 and hydrochloride thereof; vitamin E; vitamin E acetate; vitamin B12; manganese; potassium; sodium; copper; iron; selenium; iodine; chromium; molybdenum; boron; vanadium; vitamin B5; vitamin K; inositol; calcium citrate; zinc gluconate; zinc sulfate; cupric sulfate; manganese sulfate or arginate; ferrous sulfate; selenomethionine; chromium polynicotinate; boron amino

25 acid chelate; vanadyl sulfate; retinyl palmitate; sodium ascorbate; ascorbate; cholecalciferol; d-alpha tocopherol; d-alpha tocopheryl succinate; thiamin hydrochloride; pyridoxine hydrochloride; choline; and chloride.

Some vitamins are fat soluble and others are non-fat soluble. The fat-soluble vitamins include vitamin A, vitamin D, vitamin E, and vitamin K., i.e. K1

30 (phylloquinone), K2 (menaquinone), and K3 (menadione). Vitamins that are nonsoluble in fat include the vitamin B complex vitamins, and vitamin C.

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The micronutrient core may be present at levels of at least about 1 percent by weight, preferably at least about 1.6 weight percent, more preferably at least about 2 weight percent and most preferably at least about 2.4 weight percent. In other embodiments, the micronutrient nutrient core may be present at levels of at least 2.6 weight percent and may be as high as about 4 weight percent.

The amount of micronutrients employed herein to fortify the frozen dessert products can vary. It is possible, but not necessary to fortify the frozen dessert products with a recommended daily allowance (RDA), or portion or multiple of an RDA, of any of the micronutrients or combinations thereof. In some embodiments it is preferred that the products be supplemented with of micronutrients at about 2.5% by weight of the total formula on a per serving basis of  $\frac{1}{2}$  cup, which translates to approximately 2.3g of the micronutrient.

A macronutrient is typically considered to be a protein, fat, or carbohydrate. Daily protein intake is calculated in terms of total protein, but the body uses protein in the form of individual amino acids, the building blocks from which complete proteins are made. None of the body's many different proteins, which make up enzymes, muscles, blood, organs and hormones for example, can be synthesized unless all the essential amino acids that make up a complete protein are available through the diet. Because proteins are continuously broken down in the body and because the body cannot synthesize them, the essential amino acids must be constantly replenished.

Surgery, trauma, compromised immune function, malabsorption and aging are associated with reduced nutrient stores and result in a catabolic state. Nutritional supplementation replaces or helps to maintain the body's normal level of nutrients by providing adequate proteins and other nutrients essential for tissue integrity, energy needs, wound healing, immune function, digestion and other physiological functions. The frozen dessert of the present invention may be provided to individuals who are under stress due to illness, accidents, age related eating decline or diminished appetite who may not otherwise receive the recommended daily allowance of these nutrients.

For the nutrients referenced directly above, Table 3 compares the approximate nutrient values per  $\frac{1}{2}$  cup serving for a standard ice cream and an embodiment of the invention.

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Table 3

<u>Standard Ice Cream<sup>10</sup></u>		<u>Embodiment of the Invention</u>
Protein	2g	6-9g
Vitamin D	None reported	40% DV (160 IU)
Vitamin K	None reported	25% DV (20 meg)
Vitamin E	<1% DV	100% DV (30 IU)
Vitamin B1	3%DV (0.04mg)	25%DV (0.375mg)
Vitamin B2	10% DV (0.18mg)	25% DV (0.425mg)
Vitamin B3	< 1% DV	25% DV (5mg)
Vitamin B6	None Reported	50% DV (1mg)
Vitamin B12	None Reported	50% DV (3mcg)
Calcium	10% DV (100mg)	40% DV (400mg)
Magnesium	2% DV (7.5 mg)	33% DV (132mg)
Zinc	None Reported	33% DV (5mg)
Copper	<2% DV	33% DV (0.66mg)
Selenium	None Reported	50% DV (35mcg)

Lipids provide energy and essential fatty acids, and enhance absorption of the fat soluble vitamins such as vitamin A, vitamin D, vitamin E, and vitamin K. A frozen dessert is able to provide a wide variety of essential and nonessential fatty acids because the low storage temperatures help to minimize heat induced oxidative rancidity. Some polyunsaturated fats are as essential to proper nutrition as vitamins and minerals, because the body cannot synthesize them. These essential fatty acids (EFA) exhibit a myriad of physiological functions. For instance, EFAs produce hormone-like compounds, maintain cell membrane function, regulate pain, inflammation and swelling, dilate and restrict blood vessels, mediate immune responses, regulate smooth muscle responses, prevent blood clots, regulate blood pressure and nerve transmission, regulate cholesterol levels, and moderate depression. Other fats such as medium chain triglycerides are absorbed by the intestinal tract without emulsification by bile acids and are more rapidly taken up and metabolized by tissues than long chain fatty acids. Conjugated linoleic acid (CLA) is mainly found in milk fat, especially from grass fed cows, and sunflower oil. CLA has been demonstrated to be a potent anticarcinogen and

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more recently has been demonstrated to inhibit the body's mechanism for storing fat, causing the body to utilize fatty reserves for energy. Other fats such as plant fats known as sterols and sterolins exhibit potent anti-inflammatory and immune modulating properties. These fats may be derived from a variety of plant sources such as seeds, nuts, herbs, spices, and fruits.

Fat free and low fat dairy products lack many essential fatty acids which are important nutrients. The frozen dessert of the invention may be supplemented with fatty acids such as CLA, gamma linolenic acid (GLA) acids, high oleic oils such as canola, and sunflower, long chain fatty acids such as docosahexaenoic acid (DHA) and eicosapentaenoic (EPA) to produce a substance with enhanced nutritional properties. Oils such as rice bran oil contain fractions called unsaponifiables, which supply gamma oryzanols and tocotrienols with vitamin E activity and other biological roles such as reduction of cholesterol synthesis and supper antioxidant potency. Flax and evening primrose are examples of other supplemental oils that may be used to expand the functional and medical food value of the invention. Other fat nutrients which can be added to the ice cream are phytosterols such as beta-sitosterol, stigmasterol, and campesterol. Phytosterols are found in many grains and seeds and include, but are not limited to, steryols, stanols, and there esterified derivatives. These compounds have been useful for lowering serum cholesterol and inhibiting prostate and colon cancers.

The frozen dessert of the invention may include approximately 0-20 grams of fat per four fluid ounce serving. Thus, the ice cream can be fortified with approximately 0-20% fat. The fat may be obtained from sources such as dairy (cows, goats, sheep etc.); seeds such as sunflower, canola, pumpkin, safflower, soy, rice borage; nuts such as walnuts, almonds, macadamia, coconut, apricot kernel; legumes such as peanut, soy; other plants such as olive, rosemary, oregano; fish oils; sea algae oils, etc. A preferred range of fat in the ice cream product is about 3%-16%.

Proteins useful according to the invention are any suitable protein typically used in nutritional formulations. Protein sources include, but are not limited to, whey protein isolate, whey protein concentrate, whey powder, egg, soy milk powder, soy concentrate, soy protein, rice protein, caseinate (e.g., sodium caseinate, sodium calcium caseinate, calcium caseinate, potassium caseinate), animal proteins, vegetable proteins,

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and mixtures thereof. Proteins are generally incorporated in an amount ranging from 2-10 grams per 4 fluid ounce serving.

In addition to the nutrients described above, some natural – herbal sources of nutrients can be incorporated. For instance, Green tea catechins are associated with lowering blood cholesterol and are also known to be scavengers of free radicals and chelators of metals in the body, making them effective antioxidant nutrients. Cayenne helps restore proper functioning of the body. One of the key active ingredients in cayenne is capsaicin, which is responsible for invigorating the body, stimulating blood flow, promoting sleep and aiding in digestion. The fruit of the cayenne pepper also contains flavonoids, magnesium, phosphorous, sulfur, potassium, iron and calcium, and is high in vitamins A, B-complex and C. Ginger has antispasmodic properties and is useful for alleviating muscular and psychological tension, reducing inflammation, aiding in circulation, as well as having antiemetic and has analgesic properties. The ginger rhizome contains calcium, iron, magnesium, phosphorous, sodium, potassium and vitamins A, B-complex and C. Kava kava has antianxiety properties, as well as muscle relaxant and analgesic activity. St. John's wort has antispasmodic, antidepressant, anti-inflammatory and analgesic properties. St. John's wort includes components such as flavonoids, carophyllene, hypericin and pseudohypericin. Eleutherococcus senticosus (Siberian Ginseng) is an adaptogenic herb known to improve mood, attention, energy and a sense of well being. It is also known to be immunostimulatory and useful to treat stress and fatigue. Panax Ginseng is known to stimulate the anterior pituitary to release ACTH in a non-stressed state thereby increasing overall alertness and well being. The addition, in combination with the ginsengs of licorice root with its well known multiple actions including adrenocorticoid-like activity also supports adrenal function. Chickweed has anti-inflammatory, body invigorating and stimulating properties. Chickweed contains vitamin C, flavonoids, coumarins and triterpenoid saponins.

Additional information on herbal nutrients can be found in books such as the Encyclopedia of Medicinal Plants, Andrew Chevallier (1996); The Complete Family Guide to Natural Home Remedies, edited by Karen Sullivan (1997); and The Complete Family Guide to Homeopathy, by Christopher Hammond (1995).

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The frozen dessert may include other optional ingredients typically present in conventional frozen desserts such as stabilizers e.g., stabilizing gums, water-binding gums, gelling agents, and insoluble blocking agents. Stabilizers produce a smoothness in the textural properties of the product, retard or reduce ice crystal growth during storage of the product, provide uniformity in the product and resistance to melting. Stabilizers typically function through their ability to form gel structures in the water or their ability to combine with the water by hydration. Stabilizers include but are not limited to sodium alginate, propylene glycol alginate, calcium sulphate, gelatin, gum acacia, guar gum, gum karaya, locust bean gum, gum tragacanth, carrageenan and salts thereof, xanthan gum, microcrystalline cellulose, cellulose ethers such as methyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, carboxymethyl cellulose and its sodium salt, as well as mixtures of these stabilizers. Preferred stabilizers are carrageenan, xanthan gum, locust bean gum, guar gum, and mixtures thereof. Water-binding gums include, but are not limited to, locust bean gum, guar gum, propylene glycol alginate, tara gum, sodium carboxymethyl cellulose, and other cellulose ethers. Gelling agents include, but are not limited to, gelatin, xanthan gum, carrageenan, sodium alginate, and pectin. The amount of stabilizer included in the frozen dessert is typically in an amount of up to about 1% in a non fat product and about 0.1 – 0.5% for other ice cream mixes. In other embodiments, the level of stabilizer may exceed 1% by weight.

Emulsifiers are added to improve the dispersal of fat, control agglomeration of fat globules after homogenization, aid in the inclusion of air during freezing, increase resistance to melting and impart dryness to the extruded product. Emulsifiers include, but are not limited to, mono- and diglycerides, distilled mono-glycerides and drying agents such as polysorbate 80, polysorbate 65, and ethoxylated mono- and diglycerides. Emulsifiers are generally present in an amount between 0.05% and 0.2% by weight of the total product.

Lecithin is also known to be an effective emulsifier. Lecithin is a phospholipid complex commercially extracted from soy beans and other plant sources. An embodiment of the invention exceeds 0.2% in order to provide supplemental levels of phosphatidylcholine. Egg yolk solids, another optional ingredient of the frozen dessert, provide large amounts of lecithin. Custard type ice creams and French Vanilla ice



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creams have a unique smoothness attributed to the presence of lecithin in the added egg yolk solids. Egg yolk solids may be obtained from, for example, liquid egg yolks, frozen egg yolks, dried egg yolks, liquid whole eggs, frozen whole eggs, sugared frozen egg yolks, salted frozen egg yolks, dried whole eggs, or combinations of the foregoing egg yolk substances.

Preservatives may also be added to extend product shelf life. Preservatives include, but are not limited to, potassium sorbate, sodium sorbate, potassium benzoate, sodium benzoate, and calcium disodium EDTA.

The frozen desert product may be formulated by culturing the compositions of the present invention with a bacterial culture such as lactic acid-producing bacteria *Lactobacillus bulgaricus* and *Streptococcus thermophilus* or by directly adding live cultures after pasteurization. Other examples of probiotic organisms include, but are not limited to, *Bifidobacterium* spp., *Lactobacillus acidophilus* and *Bifidobacterium bifidum*. As used herein, the term "probiotic" refers to a mono or mixed culture of live microorganisms, that when applied to man or animal, beneficially affects the host by improving the properties of the indigenous microflora, such as *bifidobacterium*. Probiotic microorganisms may also include bacteria that produce therapeutic yogurts. For example, *str.salivarius* ssp. *Thermophilus*, *Lb. Acidophilus*, *B. bifidum*, in therapeutic yogurts, survive transit through the stomach, remain active in the presence of bile, and have the ability to colonize the intestine. The frozen yogurt may also be formulated from organic milk that may contain microorganisms such as *S. Thermophilus*, *L. Bulgaricus*, *L. Acidophilus*, *Bifidus*, *L. Casei*, and *L. Reuteri*. As used herein, the term "prebiotic" refers to a non-digestive food that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon, such as, fructooligosaccharides. Fructooligosaccharides (FOS) promote the proliferation of *bifidobacteria* and *lactobacilli* in the digestive tract. The levels of less desirable organisms such as *clostridia*, *bacteriosides*, and *coliforms*, appear to be reduced. Moreover, butyric acid, a short chain fatty acid (SCFA) is produced by the *bifidobacteria* fermentation of FOS. This SCFA is the main energy source for colonic epithelium.

Another embodiment of the present invention utilizes space for solids such as dietary fibers which are uncharacteristic of ice cream. Insoluble fibers such as

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cellulose, lignin, hemicelluloses, insoluble pectins and enzyme resistant starches do not dissolve in water and help to increase intestinal transit times. Soluble fibers such as soluble gums (including b-glucan), soluble pectins, and other soluble polysaccharides can decrease cholesterol absorption; delay the absorption of glucose in the small intestine; and delay gastric emptying and increase the satiety value of food.

Once the components are mixed in the mixing tank, the mixture can be subjected to pasteurization and homogenization. When the pasteurizer is of the batch type, homogenization follows immediately afterwards. In a continuous flow system, homogenization may be required to occur prior to pasteurization. Homogenization generally occurs in a two stage homogenizer with a pressure of about 2500-3000 psi in the first stage and a pressure of about 500 psi in the second stage for ice creams with 8% fat or less. As the fat content increases the first stage pressure typically decreases, while the second stage pressure usually remains around 500 psi. The homogenized mix is then pasteurized according to FDA requirements. Pasteurization is a process in which the mix is heated to a temperature of approximately 175 °F to about 185 °F for about 25 to about 30 seconds in a high temperature-short time (HTST) system. Batch pasteurization heats the mix to a lower temperature, approximately 150 °F, and a longer time, 30 minutes. Other systems such as higher-heat-short time (HHST) have a shorter processing time and higher processing temperature.

Viscosity of the ice cream mix may be a major determination in specifying pasteurization parameters. A mix may be so viscous as to cause the flow within the pasteurizer to be affected, less turbulent. This may require extending the tube length of the pasteurizer and/or decreasing the pumping rate or increasing the processing temperature. Also, because of the lack of turbulence within the heating tube, the quality of the mix nearest the wall of the holding tube may be compromised in quality due to the extended heat time. Hence a processor may incur increased processing costs, reduced plant capacity and possibly additional equipment. The invention allows, in effect, a formulator to add significantly more solids to an ice cream mix or ice cream like mix than would be understood by those skilled in the art. This is accomplished without adversely impacting manufacturing costs or capacity

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After pasteurization and homogenization, the mixture is cooled to about 40 °F or less and stored in a holding tank at that temperature for anywhere between several hours and a day.

After storage, either part or all of the mixture is transferred to a flavor tank  
5 where flavoring is added. As used herein a flavoring agent refers to compounds which impart flavors, referred to as flavorings, coloring agents, spices, nuts, candy, cookie crumbs, whole or comminuted food pieces, purees, extracts, concentrates and essences, and can be derived from natural and/or synthetically produced sources. Flavorings can be in the form of flavored extracts, volatile oils, chocolate flavorings, caramel  
10 flavorings, peanut butter flavoring, vanilla or any commercially available flavoring such as strawberry, raspberry, cherry, lemon-lime, cranberry, and blueberry flavorings. Other Examples of useful flavorings include but are not limited to pure anise extract, imitation banana extract, imitation cherry extract, chocolate extract, pure lemon extract, pure orange extract, pure peppermint extract, imitation pineapple extract, imitation rum  
15 extract, imitation strawberry extract, or pure vanilla extract; or volatile oils, such as balm oil, bay oil, bergamot oil, cedarwood oil, cherry oil, cinnamon oil, clove oil, or peppermint oil; peanut butter, chocolate flavoring, butterscotch or toffee.

The flavoring agents can be fruit or non-fruit flavoring agents and may be natural or synthetic. Examples of suitable natural flavorings include: (1) citrus and  
20 noncitrus fruit flavors (e.g., whole or comminuted fresh fruit, fruit purees, fruit concentrates, extracts or essences, candied or glazed fruits, and dried fruits); (2) sugar-free versions of such fruit flavorings; (3) flavors derived from botanicals; (4) spices; (5) chocolate, cocoa or chocolate liquor; (6) coffee; (7) natural flavorings obtained from vanilla beans; (8) nuts, including nutmeats and nut extracts from pecans, walnuts,  
25 almonds, pistachios, filberts and peanuts. Other sources of natural flavorings include liqueur flavorings such as alcohol, whiskey and other distilled beverages, fruit brandy distillate and brandy flavor essence, and fruit liqueurs. Examples of non-natural or synthetically derived flavorings include aromatic chemicals and imitation flavors. The particular amount of flavoring substance included in the frozen dessert products of the  
30 present invention will depend upon the flavor effects desired and the particular flavoring substance used. Usually, the flavoring substance comprises from about 0.5% to about 20% of the product. In one embodiment a non-fruit flavoring ranges from

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about 0.5% to about 4% where the preferred embodiment being about 1% to about 1.5% by weight of the formula. In another embodiment, a fruit flavoring may range from about 5% to about 20% and more preferably from about 11% to about 16% by weight.

5           After addition of the flavoring agent, the material is frozen and transferred to containers. The freezing process may be accomplished using any type of standard ice cream freezer equipment. For instance, the mixture may be agitated and extruded at about 20 °F to about 25 °F. For example, the homogenized pasteurized mixture of the present invention can be partially frozen or solidified by using a batch freezer,  
10 continuous freezer, low temperature continuous freezer, a soft serve-type freezer, or a counter-type freezer. The particular temperature and time conditions for carrying out this partial freezing step can vary greatly depending upon the type of freezer used. For example, the homogenized pasteurized mixtures of the present invention can be partially frozen at temperatures in the range of from about 15 °F to about 28 °F. (about  
15 -9.4 °C to about -2.2 °C.) over a period of from about 24 seconds (e.g., continuous or low temperature continuous freezer) to about 10 minutes (e.g., batch or counter freezer). During partial freezing, it is often desirable to agitate, aerate and/or whip the mixture to incorporate air to provide the desired amount of overrun. The particular amount of overrun obtained can be any level appropriate for conventional frozen  
20 dessert products, in particular ice cream products. However, the incorporation of air compromises the added nutritional value.

          The extruded material is preferably in a semi-solid state for incorporation into containers. Once in the container, the frozen dessert may be held in a freezer, e.g., at  
25 about -30 °F, for about 1 to 2 hours. The above are examples of homogenization, pasteurization, and freezing processes. These methods may be accomplished by any equivalent method for making ice cream known in the art.

          The products produced according to the methods of the invention are useful for the general support and/or improvement of nutritional wellbeing as well as an aid in the  
30 treatment of specific disorders. For example, the frozen desert of the present invention may support immune function, promote healthy intestinal flora, or support tissue repair. Additionally, the ice cream and frozen dessert products may simply be eaten as a snack

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by healthy individuals and dieters. As described in more detail in the examples section, it has been demonstrated that the products of the invention are useful for enhancing nutritional intake by those at risk of malnourishment such as the elderly. Likewise, the products may be useful for enhancing nutritional intake and meeting established dietary requirements, may stimulate the immune system, may be suitable for both insulin and non-insulin dependent diabetics, may enhance anti-oxidant and a variety of other physiological benefits.

Many methods are known in the art for determining the palatability of a food product. Some of these methods assess flavor and others assess odor. One method is referred to as the average organoleptic taste and/or odor detection threshold evaluation method. As used herein, the "average organoleptic taste and/or odor detection threshold evaluation" is a measure for assessing the relative taste and/or odor or consistency of a frozen dessert product. The relative amount of taste and/or odor of a food product is quantified as a threshold required for an average group of persons to taste and/or smell an unpalatable or unpleasant flavor or odor as compared to the level or amount of a control. In the case of a frozen dessert of the invention, the suitable controls are non-fortified ice cream (palatable taste) or fortified ice cream prepared by methods other than the methods of the invention (unpalatable taste).

Briefly, various samples of a frozen dessert product i.e., a control frozen dessert or the frozen dessert of the invention are arranged for testing by groups of individuals. Prior to each testing, the sample is isolated from the other samples. The subject to be tested is then given a series of control dessert samples (of predetermined increasing or decreasing palatability) and asked to taste and smell the sample. The subject then rates the sample on a relative scale (i.e., 1 to 10) for palatability. The order of testing is randomized between subjects. All testing is conducted by a single tester. A threshold concentration at which a subject first detects a palatable or unpalatable taste is established for each subject. This threshold value can then be used to analyze the values obtained for the same type of test performed for the test frozen dessert compositions of the invention.

The above described assay is provided for exemplary purposes only. Any assay ordinarily used in the art may be sufficient to determine whether a frozen dessert is palatable compared to controls. Other assays for measuring and comparing the odor

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and taste of different compounds are disclosed in US Patent Nos. 4,381,402, 4,180,589, 5,482,855 and 5,571,519.

The present invention is further illustrated by the following Examples, which in no way should be construed as further limiting.

5

Example I

Vanilla

Percent by Weight

	Milk – 3.5%	67.6
	Fructose	11.3
	Supplemental Oils	4.5
	Whey Concentrate	4.4
	Sucrose	3.3
	Micronutrients	2.4
	Rice Syrup – 26DE	2.2
	Non Fat Dry Milk	1.8
	Prebiotic	0.5
	Lecithin	0.3
	Stabilizer	1.4
	Citric Acid	0.3
		100.00

## Method: Mix Making

- 10        1)    Liquefy milk and sugars together
- 2)    Add oils and continue liquefy
- 3)    Add whey protein, emulsifier, milk powder, stabilizers, guar gum and cellulose
- 4)    Add pre-blended mix of micronutrients and citric acid and complete
- 15        liquefying
- 5)    HTST pasteurization of 185°F for 30 seconds – Homogenize at 1500/500 psi
- 6)    Hold for minimum of 4 hours before flavoring and freezing
- 7)    pH target 7.0; Range 6.8 – 7.2

## 20    Flavoring the Mix:

Add: 98.57% mix

Add: 1.39 vanilla flavor

Add: 0.04% probiotic

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100.00%

Freezing: Freeze to 19°F – 20°F (or 6.7°C)

Overrun is 35%

Storage: 10°F – 20°F Below Zero (-25°C to -30°C)

5

Example II

Chocolate Mint (Soy based) Frozen Dessert:

Percent by Weight

Soy Milk Concentrate, 18% solids	43.8
Water	25.8
Fructose	12.0
Supplemental Oils	5.0
Sucrose	3.9
Rice Syrup	2.5
Cocoa	2.4
Micronutrients	2.34
Lecithin	0.3
Citric Acid	0.3
Prebiotic	0.6
Stabilizer	1.0
	100

Method: Mix Making

- 10      1) Liquefy soy milk and sugars together
- 2) Add oils and continue to liquefy
- 3) Add cocoa, stabilizers, emulsifier and guar gum
- 4) Add pre-blended mix of micronutrients and citric acid and complete  
liquefying
- 15      (a) Alternatively mix the citric acid (dry) with a portion of the  
         sugars. Add micronutrients and citric acid sugar combination in close  
         proximity to each other or by alternating adding a portion of the  
         micronutrients followed by the citric acid and sugar mix.
- 5) HTST pasteurization at 185°F for 30 seconds.
- 20      6) Homogenize at 1500/500 psi
- 7) Hold for a minimum of 4 hours before flavoring and freezing
- 8) pH target 6.9 Range 6.8-7.0

Flavoring the Mix: Percentages based on weight

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99.19% Soy mix

0.81% Flavors

100.00% Total

Freezing: Freeze to 19°F – 20°F

5 Overrun is 35%

Storage: 10°F – 20°F below zero (-25°C to -30°C)

Example III

10	Lemon – Lime Frozen Dessert:	Percent by Weight
	Lemon-Lime Concentrate	3.1
	Water	64.1
	Whey Concentrate	8.3
	Maltodextrin	8.2
	Fructose	6.7
	Sucrose	5.8
	Micronutrients	1.8
	Supplemental Oils	1.5
	Stabilizer	0.3
	Malic Acid	0.2
		100.00

## Method: Mix Making

- 1) Add fruit concentrate, water and sugars and liquefy
- 2) Add oils and continue to liquefy
- 15 3) Add whey protein and stabilizer and continue to blend
- 4) Add micronutrients and malic acid in close proximity or pre-blend these ingredients prior to adding mix
- 5) HTST pasteurization at 185°F for 30 seconds
- 6) Hold for a minimum of 4 hours before flavoring and freezing
- 20 7) Homogenize at 1500/500 psi
- 8) pH target 4.5; range 4.4 – 4.6

## Flavoring the Mix by Weight

98.80% Lemon-Lime Mix

0.20% Natural Flavors

25 100.00

Freezing: Freeze to slurry of 23°F (-5°C)



- 30 -

Fill 4 fl oz mold to desired weight – 130g

Freeze in brine solution to –40°C

Overrun is 30%

Storage: 10°F – 20°F below zero (–25°C to –30°C)

5

Example IVChocolate-Mint (Soy-Whey Base):

## Percent by Weight

Water	60.6
Soy Milk Powder, 35% protein, 20% fat	8.7
Fructose	12.2
Supplemental Oils	5.0
Sucrose	3.9
Cocoa	2.4
Micronutrients	2.4
Rice Syrup	2.2
Whey Concentrate – No Lactose	1.3
Lecithin	0.3
Prebiotic	0.5
Stabilizer	0.2
Citric Acid	0.3
	100

## Method: Mix Making

- 10      1) Liquefy water and sugars together
- 2) Add oils and continue to liquefy
- 3) Add soy powder, cocoa, stabilizers, emulsifier, and guar gum
- 4) Add pre-blended mix of micronutrients and citric acid and complete  
         liquefy
- 15      a) Alternatively mix the citric acid (dry) with a portion of the  
         sugars. Add micronutrients and citric-acid sugar combination in  
         close proximity to each other or by alternating adding a portion  
         of the micronutrients followed by the citric acid and sugar mix.

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- 5) HTST pasteurization at 185°F for 30 seconds
  - 6) Homogenize at 1500/500 psi
  - 7) Hold for a minimum of 4 hours before flavoring and freezing
  - 8) pH target 6.9; Range 6.8-7.0
- 5 Flavoring the Mix: Percentages based on weight
- 99.2% - Soy Mix
- 0.8% Flavors
- 100.00% Total
- Freezing: Freeze to 19°F – 20°F
- 10 Overrun is 35%
- Storage: 10°F – 20°F below zero (-25°C to -30°C)

Example V

## 15 Hi Protein Chocolate (Dairy) Percent by Weight

Milk – 3.4%	65.6
Fructose	11.8
Whey Concentrate	6.1
Supplemental Oils	4.4
Sucrose	3.7
Micronutrients	2.4
Cocoa	2.2
Rice Syrup	1.3
Non Fat Dry Milk	1.1
Prebiotic	0.5
Citric Acid	0.4
Stabilizer	0.2
Lecithin	0.3
	100

## Method: Mix Making

- 1) Liquefy milk and sugars together
- 2) Add oils and continue to liquefy
- 20 3) Add whey protein, cocoa, emulsifier, milk powder and stabilizer,
- 4) Add pre-blended mix of micronutrients and citric acid and complete liquefying

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- 5) HTST pasteurization at 185°F for seconds – Homogenize at 1500/500 psi
  - 6) Hold for minimum of 4 hours before flavoring and freezing
  - 7) pH target 7.1; Range 7.0 – 7.2
- 5 Flavoring the Mix: Percentages by Weight
- 99.74% Mix  
0.22% Flavor  
0.04% Probiotic  
100.00%
- 10 Freezing: Freeze to 19°F –20°F (or 6.7°C)  
Overrun is 35%
- Storage: 10°F –20°F Below Zero (-25°C to –30°C)

15 Example VI

Lemon – Lime Frozen Dessert:	Percent by Weight
Lemon-Lime Concentrate	3.4
Water	69.9
Whey Concentrate	8.3
Maltodextrin	7.5
Fructose	3.7
Sucrose	3.5
Micronutrients	1.7
Supplemental Oils	1.5
Stabilizer	0.3
Malic Acid	0.2
Stevia	0.04
	100.00

## Flavoring the Mix: Percentages by Weight

- 20 99.0% Lemon-Lime Mix  
1.0% Natural Flavors

Market Test

- 25 A 90 day market test was conducted in several long term care and acute care facilities and a children's day program that included more than 300 individuals. The

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primary purpose of the test was to determine the acceptance level of a nutrient dense meal supplemental ice cream formulated and manufactured according to the invention. The employees of each healthcare facility tracked the acceptance. In all cases, product acceptance was measured by a rigorous standard that required 100% of a four fluid ounce serving to be consumed, to be tabulated as "accepted" by the consumer. The products tested were both dairy and non dairy embodiments of the invention, a total of five flavors. Acceptance of each flavor exceeded 80% and in some cases, such as vanilla, approached 90%.

#### 10 Clinical Study

A pilot trial was conducted to evaluate the taste, acceptability, tolerance, and efficacy of the nutritional frozen dessert of the present invention in facilitating weight maintenance and gain in an at risk elderly population. An at risk elderly population is defined as individuals at nutritional risk for involuntary weight loss. Involuntary or unintentional weight loss is defined as a weight loss of >5% of body weight in the past month, >7.5% in the last 60 days, or >10% in the last 90 days. Individuals whose body mass index (BMI) is <24 [weight kg/height m<sup>2</sup>] are at increased risk of developing pressure ulcers, increased risk of morbidity, mortality and functional decline.

20 Twenty three subjects between the ages of 76 and 94 (average age 85 years) were chosen from the residents of a skilled nursing and rehabilitation facility. The subject population included six males and seventeen females, ten of whom had been diagnosed with dementia and four of whom had diabetes. Individuals were included if they had experienced a weight loss of at least 5% of body weight in the past month and/or were below ideal body weight at the time of enrollment in the study. All subjects were considered to be nutritionally at risk for further weight loss and had been prescribed additional nourishments, prior to enrollment in the study. No laboratory data was consistently available to correlate depleted protein stores.

30 Four flavors of the nutritious frozen desert of the present inventions were offered as dairy based choices. There was one non-dairy soy based choice. The dairy choices provided a typical micro and macro-nutrient profile per serving as detailed in Table 4.

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Table 4: % of Daily Values based on a 2000 Calorie Diet			
Per 4 fl oz - 118 ml serving			
			9
	Calories	170	
	Total Fat (g)	7	11
	Saturated Fat (g)	4	19
5	Total Carbohydrates (g)	22	7
	Dietary Fiber (g)	2	8
	Sugars (g)	16	
	Protein (g)	6	12
	% DV		
10	Vitamin A	33	Calcium 40
	Vitamin D	40	Phosphorus 25
	Vitamin E	100	Magnesium 33
	Vitamin K	25	Iron 25
	Vitamin C	100	Iodine 25
15	Thiamin	25	Zinc 33
	Riboflavin	25	Copper 33
	Niacin	25	Manganese 33
	Vitamin B6	50	Chromium 33
	Vitamin B12	50	Selenium 50
20	Biotin	25	Molybdenum 33
	Folic Acid	50	Pantothenic Acid 33

Subjects were offered the nutritional frozen dessert three times a day. A frozen single-serve cup (4 fl oz) was placed on both the lunch and dinner trays and a third serving was offered by licensed nurse assistants (LNA) at the afternoon nourishment pass. LNAs maintained food intake records and meals/snacks were recorded by percent consumed. A registered dietitian calculated the calories offered and actually consumed on a weekly basis by averaging the daily intake from the food records. The general and therapeutic diets offered in this study were calculated to provide 2000 calories with 75 grams of protein (15% of total calories) per day.

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Weights of subjects were obtained and recorded weekly by a specially trained LNA who had completed all the weigh-ins in the facility for the past five years. An ARJO tub cart scale model number 202-200 (available from ARJO of Roselle, Illinois) was used to obtain weights. All weights were consistently assessed in the afternoon.

5 Analysis of the offered diets were completed at baseline, throughout the study period and for a three month follow-up period. The caloric and dietary protein values of diets offered to subjects were consistent during this time period.

Of the twenty-three subjects initially selected, fourteen completed the study. The remaining nine subjects did not complete the study for a variety of reasons: five

10 were lost due to death (unrelated to the study); three were discharged from the facility and one had an enteral feeding (PEG) tube placed. The fourteen subjects who completed the study were three men and eleven women. The mean age of the subjects was  $85 \pm 5.6$ ; mean height was  $64 \text{ (in)} \pm 3.1$ ; mean weight was  $130.8 \text{ (lb)} \pm 28.9$ ; and the mean BMI was  $22.2 \pm 3.4$ . The study ran for 12 weeks from February 2001 through

15 April, 2001. The subjects averaged 11 weeks of consuming the nutritional frozen dessert with a range of 9 to 12 weeks.

Eighty-six percent of subjects (12 individuals) were able to maintain or gain weight during the study period. Anthropometric data during the three months prior to starting the study showed that weight changes were not significant in this group of

20 subjects ( $p > 0.4$ ). Data during the 9 to 12 weeks of consuming the frozen dessert showed 6 subjects experienced a weight gain, (defined as  $> 2$  pounds gain), six subjects maintained their weight (defined as less than or equal to 2 pounds gain or loss) and two subjects experienced weight loss (defined as  $> 2$  pounds loss). The weight gain range in the six subjects who gained weight was 4 to 13 pounds with a mean of 6 pounds, and

25 in the two who lost weight, the range of weight loss was 5 to 7 pounds with a mean of 6 pounds. Data collected after the nutritional frozen dessert was no longer provided showed that subjects lost a significant amount of weight during the next three months ( $p = 0.044$ ) despite being offered other nourishments of equivalent caloric value. After the trial during May through June 2001, there was a mean weight loss of 3.93 pounds,

30 compared to a mean weight gain of 1.64 pounds from baseline through week 9 of the trial during the months of February through April 2001. The difference ( $p = 0.032$ ) in mean weight change after the trial was significant.

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The nutritional frozen dessert contributed between 453 to 525 calories per day to the subjects' total caloric intake. Dietary analysis of actual foods and nourishments consumed during the study period determined that the average daily caloric intake for subjects who gained weight was 1859 calories per day with the frozen desserts supplying 28% of the total daily caloric intake. The caloric intake of subjects who maintained weight was 1737 calories per day with 26% of these calories supplied by the frozen dessert and of subjects who lost weight was 1228 calories with 37% of these calories supplied by the frozen dessert.

During the trial, the four subjects with diabetes had no change in blood sugar control during the trial as detailed in Table 5.

Table 5: Diabetic Subjects - Values Determined by Finger Sticks (FS)

Subject	Diabetic Type	Pre-Study FS Values Jan. 2001	FS Values during Trial		
			Feb. 2001	Mar. 2001	Apr. 2001
Subject 1	NIDMM <sup>a</sup>				
Subject 2	IDDM <sup>c</sup>	94	NA <sup>b</sup>	70 - 102	90 - 110
Subject 3	IDDM	156 - 180	147 -	150 - 178	142 - 169
Subject 4	NIDMM	80 - 169	169	83 - 181	84 - 172
		102- 140	75 - 142	116 - 146	83 - 126
			100 -		
			132		

<sup>a</sup> Non-Insulin Dependent Diabetes

<sup>b</sup> Not Available. Physician had discontinued FS as values were in normal range. FS restarted in March.

<sup>c</sup> Insulin Dependent Diabetes

Subjects accepted the nutritional frozen dessert with meals (lunch and dinner) 100% of the time but only 59% of the time as a between meal nourishment. Acceptance is defined to mean that a subject consumed the entire 4 fl oz serving. If a portion was left and discarded or if the subject was sleeping or out of the facility when the nutritional frozen dessert was offered, it was recorded that the subject did not accept the nourishment. The acceptance rate of the nutritional frozen dessert is significant when compared to the acceptance rate of other offered items such as double strength milk based beverages, fortified puddings, soups, cereals, enriched potatoes, or gelatins as well as a variety of commercially available supplements. In-house documentation and meal monitoring has found the acceptance rate of these items generally offered in combination with one another range from 25 to 60 percent, where most residents tire

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easily of supplements, either due to taste monotony, dissatisfaction with texture or disinterest in eating and/or drinking.

The results demonstrate that at risk individuals who are consistently unable to meet their macronutrient and caloric requirements may benefit from the nutritional frozen dessert, and the dessert may be appropriate for individuals with diabetes. As noted above, skilled nursing and long-term care facilities face the challenge of providing sufficient, palatable nourishment to residents with poor appetites who are at nutritional risk for involuntary weight loss where unintentional weight loss is identified in 50% to 65% of nursing home residents increasing the risk of functional decline.

10 National statistics demonstrate that up to 23% of residents in skilled nursing facilities develop a pressure ulcer, the cost of treatment of which is extensive involving significant labor-time, medications and additional nourishment delivery to the resident, not to mention the associated pain and discomfort to the resident.

Other individuals may also benefit from receiving the nutritional frozen dessert of the present invention. Such individuals may include, but are not limited to, individuals diagnosed with a medical condition, individuals preparing for or recovering from surgery or other medical treatments, athletes, and children. For example, the subject may have a condition selected from the group consisting of osteoporosis, eczema, pregnancy, menopause, and fibriocystic breast disease. The subject may be

20 diabetic or an immune deficient subject. In one embodiment, the subject may have rheumatoid arthritis and the frozen dessert product may be fortified with gamma linolenic acid (GLA).

The foregoing written specification is considered to be sufficient to enable one skilled in the art to practice the invention. The present invention is not to be limited in scope by examples provided, since the examples are intended as a single illustration of one aspect of the invention and other functionally equivalent embodiments are within the scope of the invention. Various modifications of the invention in addition to those shown and described herein will become apparent to those skilled in the art from the foregoing description and fall within the scope of the appended claims. The advantages

30 and objects of the invention are not necessarily encompassed by each embodiment of the invention.



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All references, patents and patent publications that are recited in this application are incorporated in their entirety herein by reference.

We claim:

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CLAIMS

1. A nutritious frozen dessert comprising:
  - a base component,
  - 5 a non-fruit flavoring agent,
  - a nutrient core of at least 1% by weight of the dessert product, wherein the nutrient core includes at least one micronutrient selected from the group consisting of: Folate, Folic Acid, Magnesium, Phosphorus, Zinc, Selenium, iron, copper, chromium, molybdenum, manganese, iodine, potassium, sodium, Vitamin A, Vitamin C, Vitamin D, Vitamin B1,
  - 10 Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B12, Vitamin E, biotin, choline, chloride, Vanadium, Boron, and combinations thereof;
  - a sweetener, and
  - an acidulant.
- 15 2. The nutritious frozen dessert of claim 1, wherein the dessert includes per serving size:
  - from about 0.1 % to about 100 % of the daily value of Folate;
  - from about 0.1 % to about 80 % of the daily value of Calcium;
  - from about 0.1 % to about 80 % of the daily value of Magnesium;
  - 20 from about 0.1 % to about 80 % of the daily value of Phosphorus;
  - from about 0.1 % to about 80 % of the daily value of Zinc;
  - from about 0.1 % to about 80 % of the daily value of Vitamin A;
  - from about 0.1 % to about 250 % of the daily value of Vitamin C;
  - from about 0.1 % to about 80 % of the daily value of Vitamin D;
  - 25 from about 0.1 % to about 100 % of the daily value of Vitamin B1;
  - from about 0.1 % to about 100 % of the daily value of Vitamin B2;
  - from about 0.1 % to about 100 % of the daily value of Vitamin B3;
  - from about 0.1 % to about 200 % of the daily value of Vitamin B6;
  - from about 0.1 % to about 200 % of the daily value of Vitamin B12; and
  - 30 from about 0.1 % to about 200 % of the daily value of Vitamin E;
  - wherein the percent daily value is based on a 2,000 calorie diet.

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3. The nutritious frozen dessert of claim 2, wherein the dessert includes per serving size:
- from about 5 % to about 50 % of the daily value of Folate;
  - from about 5 % to about 50 % of the daily value of Calcium;
  - 5 from about 5 % to about 50 % of the daily value of Magnesium;
  - from about 5 % to about 50 % of the daily value of Phosphorus;
  - from about 5 % to about 50 % of the daily value of Zinc;
  - from about 5 % to about 50 % of the daily value of Vitamin A;
  - from about 5 % to about 100 % of the daily value of Vitamin C;
  - 10 from about 5 % to about 50 % of the daily value of Vitamin D;
  - from about 5 % to about 50 % of the daily value of Vitamin B1; and
  - from about 5 % to about 100 % of the daily value of Vitamin E;
- wherein the percent daily value is based on a 2,000 calorie diet.
- 15 4. The nutritious frozen dessert of claim 2, wherein the dessert includes per serving size:
- about 50 % of the daily value of Folate;
  - about 40 % of the daily value of Calcium;
  - about 33 % of the daily value of Magnesium;
  - 20 about 25 % of the daily value of Phosphorus;
  - about 33 % of the daily value of Zinc;
  - about 33 % of the daily value of Vitamin A;
  - about 100 % of the daily value of Vitamin C;
  - about 40 % of the daily value of Vitamin D;
  - 25 about 25 % of the daily value of Vitamin B1; and
  - about 100 % of the daily value of Vitamin E;
- wherein the percent daily value is based on a 2,000 calorie diet.
5. The frozen dessert of claim 1, wherein the base component is selected from the
- 30 group consisting of: dairy, soy, rice, oats, almonds, sesame, sunflower, lupine, taro, and combinations thereof.

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6. The frozen dessert of claim 1, wherein the sweetener is crystalline fructose.
7. The frozen dessert of claim 1, wherein the acidulant is selected from the group consisting of: citric acid, malic acid, adipic acid, phosphoric acid, tartaric acid, ascorbic acid, lactic acid, lemon juice concentrate, and combinations thereof.
8. The frozen dessert of claim 7, wherein the acidulant is citric acid.
9. The frozen dessert of claim 1, wherein the acidulant is present in a range of about 0.1 weight percent to about 1.1 weight percent.
10. The frozen dessert of claim 9, wherein the acidulant is present in a range of about 0.1 weight percent to about 0.6 weight percent.
11. The frozen dessert of claim 1, wherein the sweetener is present in a range of about 0.02 to about 22 weight percent.
12. The frozen dessert of claim 11, wherein the sweetener is present in a range of about 13.0 weight percent to about 17.0 weight percent.
13. The frozen dessert of claim 6 wherein the crystalline fructose is present in a range of about 0.03 weight percent to about 13 weight percent.
14. The frozen dessert of claim 1, wherein the frozen dessert has a relative sweetness of about 23% to about 27%.
15. The frozen dessert of claim 14, wherein the relative sweetness is about 23% to about 27%.
16. The frozen dessert of claim 5, wherein the dairy base is milk or cream.

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17. The frozen dessert of claim 1, wherein the sweetener is selected from the group consisting of a high dextrose sweetener, an artificial sweetener, and a highly concentrated sweetener.
- 5 18. The frozen dessert of claim 1, wherein the flavoring agent is selected from the group consisting of: coffee, chocolate, mint, caramel, vanilla, mocha, green tea, hazel nut, ginger, coconut, pistachio, rose and combinations thereof.
19. The frozen dessert of claim 1, wherein the frozen dessert is fortified with a protein.
- 10 20. The frozen dessert of claim 19, wherein the protein is present at up to about 9g.
21. The frozen dessert of claim 20, wherein the protein is present at about 6g.
- 15 22. The frozen dessert of claim 19, wherein the frozen dessert further comprises vitamin K and calcium.
23. The frozen dessert of claim 22, wherein the frozen dessert includes per serving size:
- 20 about 9 g of protein;  
about 40 % of the daily value of vitamin D;  
about 25 % of the daily value of vitamin K;  
about 100 % of the daily value of vitamin E;  
about 25 % of the daily value of vitamin B1;
- 25 about 25 % of the daily value of vitamin B2;  
about 25 % of the daily value of vitamin B3;  
about 50 % of the daily value of vitamin B6;  
about 40 % of the daily value of calcium;  
about 33 % of the daily value of magnesium;
- 30 about 33 % of the daily value of zinc;  
about 33 % of the daily value of copper;  
about 50 % of the daily value of selenium,

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wherein the percent daily value is based on a 2,000 calorie diet.

24. The frozen dessert of claim 1, wherein the frozen dessert is fortified with a dietary fiber.

5

25. The frozen dessert of claim 1, wherein the frozen dessert is fortified with an essential fatty acid.

26. The frozen dessert of claim 22, wherein the frozen dessert further comprises  
10 vitamin A, vitamin C, phosphorus, iron, iodine, manganese, vitamin B12, biotin, folic acid, chromium, and molybdenum.

27. The frozen dessert of claim 26, wherein the frozen dessert includes per serving size:

- 15 about 7 g of protein;  
about 40 % of the daily value of vitamin D;  
about 25 % of the daily value of vitamin K;  
about 100 % of the daily value of vitamin E;  
about 25 % of the daily value of vitamin B1;  
20 about 25 % of the daily value of vitamin B2;  
about 25 % of the daily value of vitamin B3;  
about 33% of the daily value of B5;  
about 50 % of the daily value of vitamin B6;  
about 50% of the daily value of vitamin B12;  
25 about 100% of the daily value of vitamin C;  
about 33% of the daily value of vitamin A  
about 40 % of the daily value of calcium;  
about 33 % of the daily value of magnesium;  
about 33 % of the daily value of zinc;  
30 about 33 % of the daily value of copper;  
about 25% of the daily value of phosphorus;  
about 25% of the daily value of iron;

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about 25% of the daily value of iodine;  
about 33% of the daily value of manganese;  
about 25% of the daily value of biotin;  
about 50% of the daily value of folic acid;  
5 about 33% of the daily value of chromium;  
about 33% of the daily value of molybdenum;  
about 50 % of the daily value of selenium,  
wherein the percent daily value is based on a 2,000 calorie diet.

10 28. The frozen dessert of claim 1, wherein the nutrient core is a micronutrient core.

29. The frozen dessert of claim 28, wherein the micronutrient core is at least about 2%  
by weight of the dessert product.

15 30. The frozen dessert of claim 29, wherein the micronutrient core is at least about  
2.4% by weight of the dessert product.

31. The frozen dessert of claim 30, wherein the micronutrient core is at least about  
4.0% by weight of the dessert product.

20

32. A method of making a nutritious frozen dessert comprising:  
mixing a base component, a nutrient core including at least one micronutrient selected  
from the group consisting of: Folate, Folic Acid, Magnesium, Phosphorus, Zinc,  
Selenium, iron, copper, chromium, molybdenum, iodine, potassium, sodium, Vitamin  
25 A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin  
B6, Vitamin B12, Vitamin E, Vitamin K, biotin, manganese, and combinations thereof;  
and an acidulant to produce a mixture;  
pasteurizing and homogenizing the mixture, and  
freezing the pasteurized mixture to produce the nutritious frozen desert.

30

33. The method of claim 32, wherein the nutrient core includes per serving size:  
from about 0.1 % to about 100 % of the daily value of Folate;

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- from about 0.1 % to about 80 % of the daily value of Calcium;  
from about 0.1 % to about 80 % of the daily value of Magnesium;  
from about 0.1 % to about 80 % of the daily value of Phosphorus;  
from about 0.1 % to about 80 % of the daily value of Zinc;  
5 from about 0.1 % to about 80 % of the daily value of Vitamin A;  
from about 0.1 % to about 250 % of the daily value of Vitamin C;  
from about 0.1 % to about 80 % of the daily value of Vitamin D;  
from about 0.1 % to about 100 % of the daily value of Vitamin B1;  
from about 0.1 % to about 100 % of the daily value of Vitamin B2;  
10 from about 0.1 % to about 100 % of the daily value of Vitamin B3;  
from about 0.1 % to about 200 % of the daily value of Vitamin B6;  
from about 0.1 % to about 200 % of the daily value of Vitamin B12; and  
from about 0.1 % to about 200 % of the daily value of Vitamin E;  
wherein the percent daily value is based on a 2,000 calorie diet.

15

34. The method of claim 33, wherein the nutrient core includes per serving size:  
from about 5 % to about 50 % of the daily value of Folate;  
from about 5 % to about 50 % of the daily value of Calcium;  
from about 5 % to about 50 % of the daily value of Magnesium;  
20 from about 5 % to about 50 % of the daily value of Phosphorus;  
from about 5 % to about 50 % of the daily value of Zinc;  
from about 5 % to about 50 % of the daily value of Vitamin A;  
from about 5 % to about 100 % of the daily value of Vitamin C;  
from about 5 % to about 50 % of the daily value of Vitamin D;  
25 from about 5 % to about 50 % of the daily value of Vitamin B1; and  
from about 5 % to about 100 % of the daily value of Vitamin E.

35. The method of claim 34, wherein the nutrient core includes per serving size:  
about 50 % of the daily value of Folate;  
30 about 40 % of the daily value of Calcium;  
about 33 % of the daily value of Magnesium;  
about 25 % of the daily value of Phosphorus;



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- about 33 % of the daily value of Zinc;
- about 33 % of the daily value of Vitamin A;
- about 100 % of the daily value of Vitamin C;
- about 40 % of the daily value of Vitamin D;
- 5 about 25 % of the daily value of Vitamin B1; and
- about 100 % of the daily value of Vitamin E.

36. The method of claim 32, wherein the nutrient core includes per serving size:
- about 40 % of the daily value of vitamin D;
  - 10 about 25 % of the daily value of vitamin K;
  - about 100 % of the daily value of vitamin E;
  - about 25 % of the daily value of vitamin B1;
  - about 25 % of the daily value of vitamin B2;
  - about 25 % of the daily value of vitamin B3;
  - 15 about 33% of the daily value of B5;
  - about 50 % of the daily value of vitamin B6;
  - about 50% of the daily value of vitamin B12;
  - about 100% of the daily value of vitamin C;
  - about 33% of the daily value of vitamin A
  - 20 about 40 % of the daily value of calcium;
  - about 33 % of the daily value of magnesium;
  - about 33 % of the daily value of zinc;
  - about 33 % of the daily value of copper;
  - about 25% of the daily value of phosphorus;
  - 25 about 25% of the daily value of iron;
  - about 25% of the daily value of iodine;
  - about 33% of the daily value of manganese;
  - about 25% of the daily value of biotin;
  - about 50% of the daily value of folic acid;
  - 30 about 33% of the daily value of chromium;
  - about 33% of the daily value of molybdenum;
  - about 50 % of the daily value of selenium,

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wherein the percent daily value is based on a 2,000 calorie diet.

37. The method of claim 32, wherein the base component provided is selected from the group consisting of: dairy, soy, rice, oats, almonds, sesame, sunflower, lupine, taro, and combinations thereof.

38. The method of claim 32, further comprising adding sweetener prior to pasteurization.

39. The method of claim 38, wherein the sweetener is mixed with the acidulant prior to mixing the acidulant with the base component and the nutrient core.

40. The method of claim 32, wherein the acidulant is selected from the group consisting of: citric acid, malic acid, adipic acid, phosphoric acid, tartaric acid, ascorbic acid, lactic acid, lemon juice concentrate, and combinations thereof.

41. The frozen dessert of claim 40, wherein the acidulant is citric acid.

42. The method of claim 32, wherein the acidulant is added in a range of about 0.1 weight percent to about 1.1 weight percent.

43. The method of claim 42, wherein the acidulant is added in a range of about 0.1 weight percent to about 0.6 weight percent.

44. The method of claim 36, wherein the sweetener is added in a range of about 0.02 weight percent to about 22.0 weight percent.

45. The method of claim 44, wherein the sweetener is added in a range of about 13.0 weight percent to about 17.0 weight percent.

46. The method of claim 38, wherein the sweetener is crystalline fructose.

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47. The method of claim 37, wherein the dairy base is milk or cream.
48. The method of claim 38, wherein the sweetener is selected from the group consisting of a high dextrose sweetener, an artificial sweetener, and a highly concentrated sweetener prior to pasteurization.
49. The method of claim 32, further comprising adding a flavoring agent after the pasteurization step.
50. The method of claim 49, wherein the flavoring agent is a non-fruit flavoring agent selected from the group consisting of: coffee, chocolate, mint, caramel, vanilla, mocha, green tea, hazel nut, ginger, coconut, pistachio, rose and combinations thereof.
51. The method of claim 49, wherein the flavoring agent is a fruit flavoring agent selected from the group consisting of: mandarin, orange, strawberry, banana, raspberry, mango, passion fruit, lemon, lime, blueberry, cherry, cranberry, and combinations thereof.
52. The method of claim 32, further comprising adding a macronutrient selected from the group consisting of a protein, a fat, and a dietary fiber.
53. The method of claim 51, further comprising adding an acidulant after the pasteurization step.
54. A method of making a nutritious frozen dessert comprising:  
mixing a base component and a nutrient core including at least one micronutrient selected from the group consisting of: Folate, Magnesium, Phosphorus, Zinc, Selenium, iron, copper, chromium, molybdenum, iodine, potassium, sodium, Vitamin A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B12, Vitamin E, Vitamin K, biotin, manganese, and combinations thereof to produce a mixture;  
pasteurizing and homogenizing the mixture,

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adding non-fruit flavoring agent and an acidulant and  
freezing the pasteurized mixture to produce the nutritious frozen desert.

55. The method of claim 54, wherein the nutrient core includes per serving size:
- 5 from about 0.1 % to about 100 % of the daily value of Folate;
  - from about 0.1 % to about 80 % of the daily value of Calcium;
  - from about 0.1 % to about 80 % of the daily value of Magnesium;
  - from about 0.1 % to about 80 % of the daily value of Phosphorus;
  - from about 0.1 % to about 80 % of the daily value of Zinc;
  - 10 from about 0.1 % to about 80 % of the daily value of Vitamin A;
  - from about 0.1 % to about 250 % of the daily value of Vitamin C;
  - from about 0.1 % to about 80 % of the daily value of Vitamin D;
  - from about 0.1 % to about 100 % of the daily value of Vitamin B1;
  - from about 0.1 % to about 100 % of the daily value of Vitamin B2;
  - 15 from about 0.1 % to about 100 % of the daily value of Vitamin B3;
  - from about 0.1 % to about 200 % of the daily value of Vitamin B6;
  - from about 0.1 % to about 200 % of the daily value of Vitamin B12; and
  - from about 0.1 % to about 200 % of the daily value of Vitamin E;
- wherein the percent daily value is based on a 2,000 calorie diet.

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56. The method of claim 54, wherein the nutrient core includes per serving size:
- from about 5 % to about 50 % of the daily value of Folate;
  - from about 5 % to about 50 % of the daily value of Calcium;
  - from about 5 % to about 50 % of the daily value of Magnesium;
  - 25 from about 5 % to about 50 % of the daily value of Phosphorus;
  - from about 5 % to about 50 % of the daily value of Zinc;
  - from about 5 % to about 50 % of the daily value of Vitamin A;
  - from about 5 % to about 100 % of the daily value of Vitamin C;
  - from about 5 % to about 50 % of the daily value of Vitamin D;
  - 30 from about 5 % to about 50 % of the daily value of Vitamin B1; and
  - from about 5 % to about 100 % of the daily value of Vitamin E.

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57. The method of claim 55, wherein the nutrient core includes per serving size:
- about 50 % of the daily value of Folate;
  - about 40 % of the daily value of Calcium;
  - about 33 % of the daily value of Magnesium;
  - 5 about 25 % of the daily value of Phosphorus;
  - about 33 % of the daily value of Zinc;
  - about 33 % of the daily value of Vitamin A;
  - about 100 % of the daily value of Vitamin C;
  - about 40 % of the daily value of Vitamin D;
  - 10 about 25 % of the daily value of Vitamin B1; and
  - about 100 % of the daily value of Vitamin E.

58. The method of claim 54, wherein the nutrient core includes per serving size:
- about 40 % of the daily value of vitamin D;
  - 15 about 25 % of the daily value of vitamin K;
  - about 100 % of the daily value of vitamin E;
  - about 25 % of the daily value of vitamin B1;
  - about 25 % of the daily value of vitamin B2;
  - about 25 % of the daily value of vitamin B3;
  - 20 about 33% of the daily value of B5;
  - about 50 % of the daily value of vitamin B6;
  - about 50% of the daily value of vitamin B12;
  - about 100% of the daily value of vitamin C;
  - about 33% of the daily value of vitamin A
  - 25 about 40 % of the daily value of calcium;
  - about 33 % of the daily value of magnesium;
  - about 33 % of the daily value of zinc;
  - about 33 % of the daily value of copper;
  - about 25% of the daily value of phosphorus;
  - 30 about 25% of the daily value of iron;
  - about 25% of the daily value of iodine;
  - about 33% of the daily value of manganese;

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- about 25% of the daily value of biotin;  
about 50% of the daily value of folic acid;  
about 33% of the daily value of chromium;  
about 33% of the daily value of molybdenum;  
5 about 50 % of the daily value of selenium,  
wherein the percent daily value is based on a 2,000 calorie diet.

59. The method of claim 54, wherein the base component provided is selected from the group consisting of: dairy, soy, rice, oat, almond, sesame, sunflower, lupine, taro, and  
10 combinations thereof.

60. The method of claim 54, further comprising adding a crystalline fructose prior to pasteurization.

15 61. The method of claim 54, wherein the acidulant is selected from the group consisting of: citric acid, malic acid, adipic acid, phosphoric acid, tartaric acid, ascorbic acid, lactic acid, lemon juice concentrate, and combinations thereof.

20 62. The frozen dessert of claim 61, wherein the acidulant is citric acid.

63. The method of claim 54, wherein the acidulant is added in a range of about 0.1 weight percent to about 1.1 weight percent.

25 64. The method of claim 63, wherein the acidulant is added in a range of about 0.1 weight percent to about 0.6 weight percent.

65. The method of claim 60, wherein the sweetener is added in a range of about 0.02 weight percent to about 22.0 weight percent.

30 66. The method of claim 65, wherein the sweetener is added in a range of about 13 weight percent to about 17 weight percent.

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67. The method of claim 59, wherein the dairy base is milk or cream.
68. The method of claim 54, further comprising adding a sweetener selected from the group consisting of a high dextrose sweetener, an artificial sweetener, and a highly concentrated sweetener prior to pasteurization.
69. The method of claim 54, wherein the non-fruit flavoring agent is selected from the group consisting of: coffee, chocolate, mint, caramel, vanilla, mocha, green tea, hazel nut, ginger, coconut, pistachio, rose and combinations thereof.
70. The method of claim 54, further comprising adding a macronutrient selected from the group consisting of a protein, a fat, and a dietary fiber.
71. The method of claim 54, wherein the nutrient core is a micronutrient core.
72. The method of claim 71, wherein the micronutrient core is at least about 1% by weight of frozen dessert.
73. The method of claim 71, wherein the micronutrient core is at least 1.6% by weight of the frozen dessert.
74. The method of claim 54, wherein the micronutrient core is at least about 2.4% by weight of frozen dessert.
75. The method of claim 74, wherein nutrient core is at least about 4% by weight of the frozen dessert.
76. A method of treating a subject comprising administering to the subject a nutritious frozen dessert, wherein the dessert comprises:
- a base component,
  - a non-fruit flavoring agent,

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a nutrient core of at least 1% by weight of the dessert product, wherein the nutrient core includes at least one micronutrient selected from the group consisting of: Folate, Magnesium, Phosphorus, Zinc, Selenium, iron, copper, chromium, molybdenum, manganese, iodine, potassium, sodium, Vitamin A, Vitamin C, Vitamin D, Vitamin B1,  
5 Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B12, Vitamin E, biotin, choline, chloride, Vanadium, Boron, and combinations thereof;  
a sweetener, and  
an acidulant.

10 77. The method of claim 76, wherein the subject is a diabetic.

78. The method of claim 76, wherein the subject is an elderly subject.

79. A method of treating a subject comprising administering to the subject a frozen  
15 dessert product prepared by the method of claim 17.

80. A method of treating a subject comprising administering to the subject a nutritious frozen dessert, wherein the dessert comprises:  
a base component,  
20 a micronutrient core of at least 1% by weight of the dessert product, wherein the nutrient core includes at least one micronutrient selected from the group consisting of: Folate, Magnesium, Phosphorus, Zinc, Selenium, iron, copper, chromium, molybdenum, manganese, iodine, potassium, sodium, Vitamin A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin B12,  
25 Vitamin E, biotin, choline, chloride, Vanadium, Boron, and combinations thereof;  
a sweetener, and  
an acidulant.

81. The method of claim 80, further comprising a non-fruit flavoring agent.  
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82. The method of claim 81, wherein the subject is an elderly subject.



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83. A prepasteurization mixture for preparing a nutritious frozen dessert comprising:  
a base component,  
a nutrient core of at least 1% by weight at least one micronutrient selected from the  
group consisting of: Folate, Folic Acid, Magnesium, Phosphorus, Zinc, Selenium, iron,  
5 copper, chromium, molybdenum, iodine, potassium, sodium, Vitamin A, Vitamin C,  
Vitamin D, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Vitamin  
B12, Vitamin E, Vitamin K, biotin, manganese, and combinations thereof; and  
an acidulant.
- 10 84. The prepasteurization mixture of claim 80 further comprising a sweetener.
85. The prepasteurization mixture of claim 80, wherein the acidulant is selected from  
the group consisting of: citric acid, malic acid, adipic acid, phosphoric acid, tartaric  
acid, ascorbic acid, lactic acid, lemon juice concentrate, and combinations thereof.

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/16138

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A23G9/02 A23G9/30 A23G9/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 084 295 A (PETROSSIAN VANIK D ET AL) 28 January 1992 (1992-01-28)</p> <p>column 24, line 55 - line 68; example E column 15, line 65 - column 18, line 55 column 15, line 19 - line 60; examples column 13, line 22 - line 49 column 4, line 35 - line 44 column 11, line 33 - column 12, line 35 --- -/--</p>	<p>1, 5-9, 11, 12, 16-25, 29, 32, 36-42, 44-54, 58-63, 65-72, 76-85</p>

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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